OCT - 6 2000

K001742

510(K) Summary
for
Resusci® Inflate-A-Shield™ CPR Barrier

1. SPONSOR

Laerdal Medical Corporation
167 Myers Corners Rd.
Wappingers Falls, NY 12590

Contact Person: Ronald L. Weyhrauch, R.A.C.
Telephone: 914-297-7770 x234

Date Prepared: June 7, 2000

2. DEVICE NAME

Proprietary Name: Resusci® Inflate-A-Shield™ CPR Barrier
Common/Usual Name: CPR Face Shield
Classification Name: Non-rebreathing valve

3. PREDICATE DEVICES

Laerdal™ Pocket Mask (K933048, Laerdal Medical Corporation)
Resusci® Patient Face Shield (K880450, Laerdal Medical Corporation)

4. DEVICE DESCRIPTION

The proposed Resusci® Inflate-A-Shield™ is a flexible face shield with an inflatable cuff that is surrounded by a non-inflatable skirt. The device contains a combination non-rebreathing valve and hydrophobic filter in the center of the cuff.

The Resusci® Inflate-A-Shield™ is supplied folded compactly in a 2.25" square tamper-evident bag. The rescuer opens the bag, unfolds the face shield, inflates the cuff*, and places the face shield over the patient's mouth. *Alternatively, the shield can also be used without inflating the cuff. Once the face shield is in place, the rescuer performs mouth-to-mouth breathing according to standard CPR procedures.

The Resusci® Inflate-A-Shield™ is designed to be disposable and discarded after a single use.

5. INTENDED USE

The Resusci® Inflate-A-Shield™ CPR Barrier is a non-invasive, non-prescription face shield with inflatable cuff and an integral non-rebreathing valve and hydrophobic filter. The face shield serves as a physical barrier, intended to prevent direct mouth contact with the patient's face when providing mouth-to-mouth resuscitation.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed Resusci® Inflate-A-Shield™, the Resusci® Patient Face Shield, and the Laerdal™ Pocket Mask all provide a physical barrier between the patient and rescuer and reduce the risk of contamination during mouth-to-mouth breathing. The Resusci® Inflate-A-Shield™ combines the flexible, compact design of the Resusci® Face Shield with the non-rebreathing valve and filter assembly of the Pocket Mask to produce a device that will fit in a pocket or hang from a keychain. The differences in device components, configuration, and materials are minor and do not affect the safety or effectiveness of the device for its intended use.

7. PERFORMANCE TESTING

Testing to measure the bacterial filtration efficiency (BFE) and viral filtration efficiency (VFE) was performed on samples of the filter material configured in a stainless steel housing intended to simulate the filter assembly. The delivery system was designed to deliver aerosol bacterial and viral challenges far in excess of what would be expected under use conditions (10^6 colony forming units and 10^6 plaque forming units for the BFE and VFE, respectively). The results confirm a 99.9408% BFE and 99.186% VFE for the Resusci® Inflate-A-Shield™.

Testing was also performed that demonstrates that the Resusci® Inflate-A-Shield™ conforms to the applicable requirements of ISO-10993-1 and General Program Memorandum G95-1 [Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"], for a surface device with limited contact duration (≤24 hours).

8. CONCLUSION

Laerdal Medical Corporation concludes that the Resusci® Inflate-A-Shield™ is substantially equivalent to the Resusci® Face Shield and Pocket Mask products. The intended uses of all three devices are identical. The differences in device components, configuration, and materials are minor and do not affect the safety or effectiveness of the device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2000

Cynthia J.M. Nolte, Ph.D.
Staff Consultant
Laerdal Medical Corporation
c/o Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K001742
Resusci® Inflate-A-Shield™ CPR Barrier
Regulatory Class: II (two)
Product Code: 73 CBP
Dated: September 20, 2000
Received: September 22, 2000

Dear Dr. Nolte:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS

inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known):

Device Name: Resusci® Inflate-A-Shield™ CPR Barrier

Indications For Use:

The Resusci® Inflate-A-Shield™ CPR Barrier is a non-prescription, non-invasive face shield, with an inflatable cuff and an integral non-rebreathing valve and hydrophobic filter. The face shield serves as a physical barrier, intended to prevent direct mouth contact with the patient's face when providing mouth-to-mouth resuscitation. The valve and filter further serve to reduce the potential for cross-contamination between the rescuer and patient.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001742

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)